Medtronic

The most objective way to diagnose GERD and optimize therapy.[2]

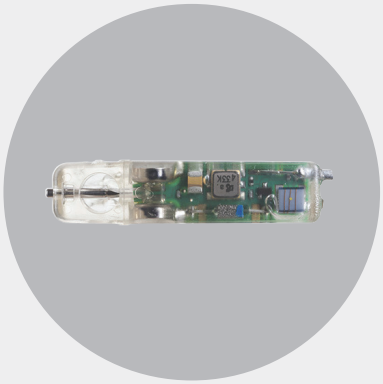
Bravo™ calibration-free reflux testing system

One in three patients on PPI's with ongoing symptoms doesn't have GERD[1]

- PPI's have been associated with several complications[2]
- Annual spending on PPI's is a large public health burden.[4]
- PPI's prescribed without a correct diagnosis further exacerbates spending.[3]

When to use Bravo™ calibration-free reflux testing system

PPI non-respondents
Inconclusive EGD



Bravo™ reflux testing off PPI's

PPI's can disrupt the process of diagnosing GERD

Prescribed PPI's are ineffective for one in three patients

Patients presenting with GERD-like symptoms can be challenging. PPI's may relieve symptoms for the majority of your patients however, one in three patients with ongoing symptoms doesn't have GERD.[1]

Long-term use of PPI's can lead to health risks

Without a clear diagnosis, long-term or over-use of PPI's can lead to serious health complications such as osteoporosis, dementia, and enteric infections.[3]

Different diseases, similar symptoms

Other conditions, such as achalasia, dysphasia, and gastroparesis mimic the symptoms of GERD. This makes patients with GERD-like conditions difficult to diagnose.

The definitive GERD diagnosis

Most patients on PPI's have negative endoscopy

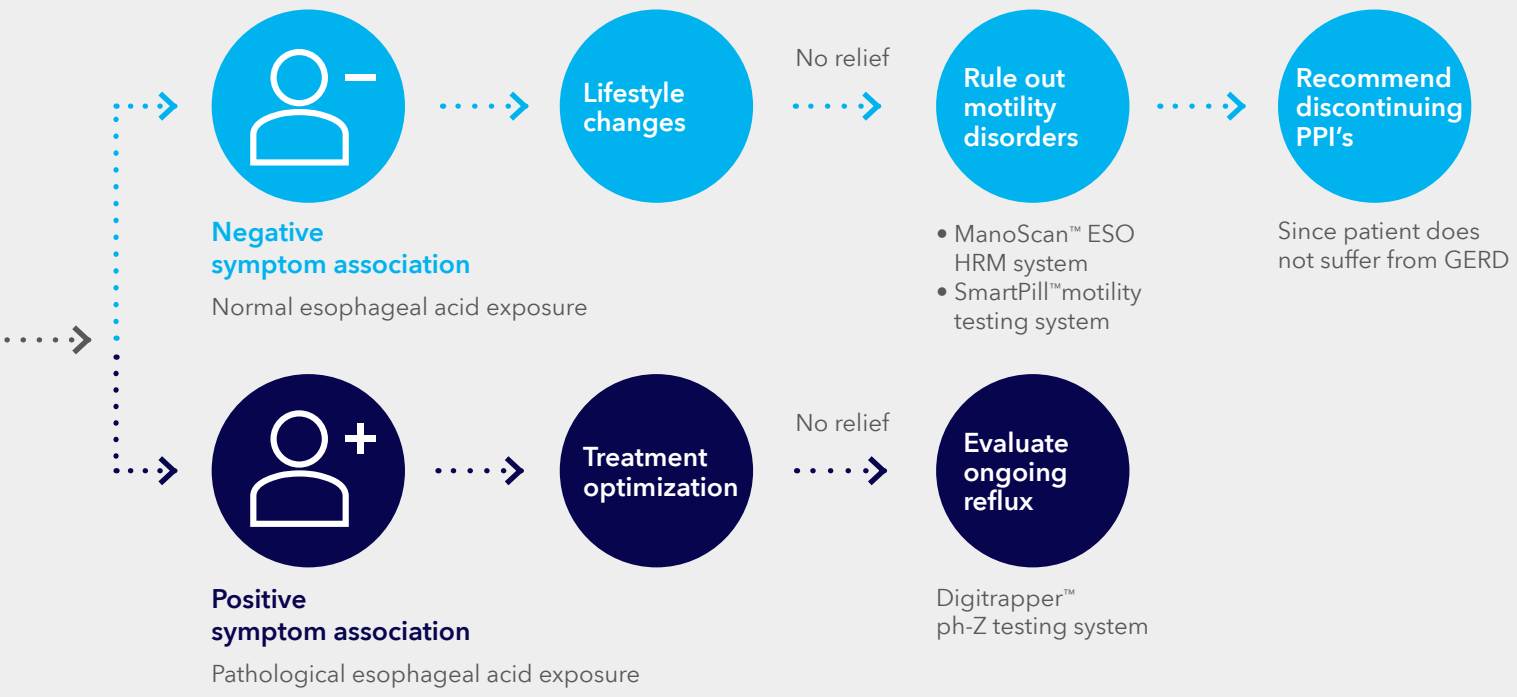
The challenge mounts when patients who don't respond well to PPI's are sent for an upper endoscopy (EGD). A significant proportion of these patients (50–70%) will result to have evidence of a normal endoscopy.[5] Further investigation is needed to objectively diagnose GERD.

Gold standard to diagnose GERD[6,7]

Ambulatory reflux testing can objectively determine if GERD is the root cause of symptoms.[2] Prompt referral after an empiric PPI trial is more cost-effective than prolonging ineffective and risky PPI use.[8] Reflux testing helps definitively diagnose GERD.[9] Most physicians rely on the Bravo™ reflux testing system to objectively diagnose GERD and determine the need for therapy.

Discontinue or optimize PPI therapy

Definitive diagnosis allows you to determine next steps in patient care whether that is further diagnosis or treatment optimization. This means you can confidently make the right treatment option or stop unnecessary therapy.



Medtronic

Trusted partner

Our powerful history and high ethical standards help establish our credibility. We collaborate with public and private payers, governments, and hospital systems interested in working together to shape and deploy value-based business models.

While we firmly believe Medtronic has a unique role to play in the move toward aligned, value-based care, we know we can do more. And we know we can't do it alone.

Only through collaboration and partnership can we all achieve the benefits of value-based healthcare.

Indications:

- The Bravo™ reflux testing system is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.
- The Reflux/Accuview software application is intended to record, store, view, and analyze gastroesophageal pH data.
- Contraindications for the Bravo™ reflux testing system include:
- Patients with pacemakers or implantable cardiac defibrillators.
- The risks of Bravo™ reflux testing system include:
- The safety and efficacy has not been established for pediatric use on patients below the age of 4.
- Patients are restricted from undergoing an MRI study within 30 days of the start of a reflux study. Use of the Bravo™ reflux testing system in an MRI magnetic field will result in damage to the system and possible patient injury.
- Undergoing an MRI while the Bravo™ reflux capsule is inside the patient's body may result in serious damage to the patient's intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of any Bravo™ reflux capsule, the patient should contact the physician for evaluation and possible abdominal x-ray before undergoing an MRI examination.
- The Bravo™ reflux capsule contains a trocar needle that is made of stainless steel. Use caution in patients with known sensitivities to the metals that are contained including chromium, nickel, copper, cobalt, and iron. Tests last from 48 to 96 hours.
- Gastrointestinal endoscopy: Potential complications include, but are not limited to: perforation, hemorrhage, aspiration, fever or infection, hypertension, respiratory arrest, and cardiac arrhythmia or arrest.
- Nasal intubation: Potential complications include, but are not limited to: sore throat, discomfort, and nasopharyngeal damage resulting in bleeding and soft tissue damage.

Contraindications:

- Patients with bleeding diathesis, strictures, severe esophagitis, varices, or obstructions.
- Patients with pacemakers or implantable cardiac defibrillators.

Risks:

- The Bravo™ reflux capsule can be attached following either endoscopy or manometry.
- Patients with bleeding diathesis, strictures, severe esophagitis, varices or obstructions.
- Aspiration, tears or perforation in the mucosa, pain or discomfort (including chest pain) associated with the capsule, premature detachment, or failure to detach, which may necessitate endoscopic removal.
- The risks of Bravo™ calibration-free reflux testing system include: premature detachment, discomfort, failure to detach, failure to attach, capsule aspiration, capsule retention, tears in the mucosa, bleeding, chest pain and perforation.
- Endoscopic placement may present additional risks.
- Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur.
- Because the capsule contains a small magnet, patients should not have an MRI study within 30 days of undergoing the Bravo™ pH test.

References

1. Herregods, TV, Troelstra M, Weijenborg PW, Bredenoord AJ, Smout AJ. Patients with refractory reflux symptoms often do not have GERD. *Neurogastroenterol Motil*. 2015;27(9):1267–73.
2. Hirano I, Zhang Q, Pandolfino JE, Kahrilas PJ. Four day Bravo pH capsule monitoring with and without proton pump inhibitor therapy. *Clin Gastroenterol & Hepatol*. 2005;3(11):1083–1088.
3. Vakil N. Prescribing proton pump inhibitors: is it time to pause and rethink? *Drugs*. 2012 5;72(4):437–445.
4. Shaheen NJ, Hansen RA, Morgan DR, et al. The burden of gastrointestinal and liver diseases. *Am J Gastroenterol*. 2006;101(9):2128–2138.
5. Vaezi M, Zehrai A, Yuksel E. Testing for refractory gastroesophageal reflux disease. *ASGE Leading Edge*. 2012;2(2):1–13.
6. Chitwood K. Perspectives on empiric and chronic proton pump inhibitor therapy. *Formulary*. 2004;39(8):406–412.
7. Sharma VK. The future is wireless: advances in wireless diagnostic and therapeutic technologies in gastroenterology. *Gastroenterol*. 2009;137(2):434–439.
8. Kleiman DA, Beninato BP, Bosworth T, et al. Early referral for esophageal pH monitoring is more cost-effective than prolonged empiric trial of proton pump inhibitors for suspectied gastroesophageal reflux disease. *J Gastrointest Surg*. 2014;18(1):26–33.
9. Gawron A, Pandolfino J. Ambulatory reflux monitoring in GERD – Which test should be performed and should therapy be stopped? *Curr Gastro Rep*. 2013;15(4):316.